

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Benser et al.	Confirmation No.:	2274
Serial No.:	10/765,625	Examiner:	Caryl Layno
Filed:	01/26/2004	Art Unit:	3766
Docket No.:	A04P1009		
For:	AUGMENTING HYPOVENTILATION		

SUBMISSION OF NEW DECLARATION AND REMARKS

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P.O. Box 1450
Alexandria, VA 22313-1450

I hereby certify that this correspondence is being
filed electronically on:

February 28, 2008


Liliana Cancino

Sir:

In the Notice of Allowability mailed December 6, 2007, the Examiner rejected the inventor declaration. Submitted herewith is a new declaration to overcome the rejection; however Applicants respectfully disagree with the rejection for the following reasons.

The Examiner alleges the inventor declaration is defective because the declaration states that the inventor acknowledges a duty to disclose information which is material "to the examination of the application" rather than information material "to patentability" as defined in Section 1.56. Applicants respectfully disagree with the Examiner's rejection of the inventor declaration.

Applicants submit that 37 CFR section 1.63 (see Exhibit A) previously required an acknowledgement of Applicant's duty to disclose information that is "material to the examination of the application". However, in a "Duty of Disclosure" rule change published at 1135 OG 13 (February 4, 1992), Rule 63 was changed so that its language tracked the "material to patentability" language of Rule 56 (See Exhibit B).

PATENT

In making this change, and in reply to Comment 38 at 1135 OG 17 (see Exhibit C), the Office stated the averments in oath or declaration forms presently in use that comply with the previous section 1.63 or 1.175 will also comply with the requirement of the new rules. The Office also stated, "Therefore, the Office will continue to accept the old oath or declaration forms as complying with the new rules." Applicants therefore submit that the inventor declaration, which complies with the requirements of Rule 63 prior to the 1992 rule change, also complies with the requirements of the current rule and should be accepted.

Moreover, the first page of the Duty of Disclosure Rulemaking (see Exhibit B) as published at 1135 OG 13 (February 4, 1992) explains that an Applicant for a patent also has a duty of candor and good faith in dealing with the Patent Office and that this duty is broader than the duty to disclose information material to patentability. Therefore, Applicants submit that the duty to disclose information material to the "examination" of the application (which includes the duty of candor and good faith) as recited in the inventor declaration for the subject application is broader than and includes the duty to disclose information material to the patentability of the application as required by the Examiner.

Applicants therefore submit that the as filed inventor declaration encompasses a broader duty of disclosure and complies with the requirements of 37 CFR 1.63. However, in the interest of moving this case to issuance, Applicants hereby submit a new declaration with the language required by the Examiner.

Respectfully submitted,

2/28/08
Date

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CUSTOMER NUMBER: 36802

code of federal regulations

Patents, Trademarks
and Copyrights

37

Revised as of July 1, 1991



EXHIBIT A

time of filing the application under this section. No copy of the prior application or new specification is required. The filing of such a copy or specification will be considered improper, and a filing date as of the date of deposit of the request for an application under this section will not be granted to the applicant unless a petition with the fee set forth in § 1.17(d)(1) is filed with instructions to cancel the copy or specification.

(f) The filing of an application under this section will be construed to include a waiver of secrecy by the applicant under 35 U.S.C. 122 to the extent that any member of the public who is entitled under the provisions of 37 CFR 1.14 to access to, or information concerning either the prior application or any continuing application filed under the provisions of this section may be given similar access to, or similar information concerning, the other application(s) in the file wrapper.

(g) The filing of a request for a continuing application under this section will be considered to be a request to expressly abandon the prior application as of the filing date granted the continuing application.

(h) The applicant is urged to furnish the following information relating to the prior and continuing applications to the best of his or her ability:

- (1) Title as originally filed and as last amended;
- (2) Name of applicant as originally filed and as last amended;
- (3) Current correspondence address of applicant.

(4) Identification of prior foreign application and any priority claim under 35 U.S.C. 119.

(5) The title of the invention and names of the applicants to be named in the continuing application.

(6) Envelopes containing only application papers and fees for filing under this section should be marked "Box FWC".

(j) If any application filed under this section is found to be improper, the applicant will be notified and given a time period within which to correct the filing error in order to obtain a filing date as of the date the filing error is corrected provided the correction is made before the payment of

the issue fee, abandonment of, or termination of proceedings on the prior corrected within the time period set, the application will be returned or otherwise disposed of; the fee, if submitted, will be refunded less the handling fee set forth in § 1.21(n).

(35 U.S.C. 6, Pub. L. 97-247)

(48 FR 2710, Jan. 20, 1983, as amended at 49 FR 585, Jan. 4, 1984; 50 FR 9380, Mar. 7, 1985; 64 FR 47512, Nov. 15, 1999)

OATH or DECLARATION

§ 1.63 Oath or declaration.

(a) An oath or declaration filed under § 1.51(a)(2) as a part of an application must:

(1) Be executed in accordance with either § 1.66 or § 1.68;

(2) Identify the specification to which it is directed;

(3) Identify each inventor and the residence and country of citizenship of each inventor; and

(4) State whether the inventor is a sole or joint inventor of the invention claimed.

(b) In addition to meeting the requirements of paragraph (a), the oath or declaration must state that the person making the oath or declaration:

(1) Has reviewed and understands the contents of the specification, including the claims, as amended by any amendment specifically referred to in the oath or declaration;

(2) Believes the named inventor or inventors to be the original and first inventor or inventors of the subject matter which is claimed and for which a patent is sought; and

(3) Acknowledges the duty to disclose information which is material to the examination of the application in accordance with § 1.56(a).

(c) In addition to meeting the requirements of paragraphs (a) and (b) of this section, the oath or declaration in any application in which a claim for foreign priority is made pursuant to § 1.55 must identify the foreign application for patent or inventor's certificate on which priority is claimed, and any foreign application having a filing date before that of the application on

Patent and Trade

which priority is claimed, day, month and year.

(d) In any application filed specified in 35 U.S.C. 119, the applicant must also make the oath or declaration that the applicant has knowledge of the prior art information which occurred date of the prior art information or PCP date of the continuation.

(35 U.S.C. 6, Pub. L. 97-247; 48 FR 2711, Jan. 20, 1983)

§ 1.64 Person making

(a) The oath or declaration made by all of the inventors except as provided in § 1.47.

(b) If the person making the oath or declaration is a sole inventor, the oath or declaration shall state that the person is the sole inventor and which the invention is claimed.

(35 U.S.C. 6, Pub. L. 97-247; 48 FR 2711, Jan. 20, 1983)

§ 1.66 Officers authorized to administer oaths.

(a) The oath or declaration may be made before any United States official authorized to administer oaths. An official seal and signature of the official administering the oath or declaration shall be placed on the application. The authority shall be in the form of a certificate of a diplomatic officer of the United States, or of an official designating a country which, by treaty, accord, or other designated officials.

the issue fee, abandonment of, or termination of proceedings on the prior application. If the filing error is not corrected within the time period set, the application will be returned or otherwise disposed of; the fee, if submitted, will be refunded less the handling fee set forth in § 1.21(n).

(35 U.S.C. 6, Pub. L. 97-247)

[48 FR 2710, Jan. 20, 1983, as amended at 49 FR 555, Jan. 4, 1984; 50 FR 9380, Mar. 7, 1985; 54 FR 47519, Nov. 15, 1989]

OATH OR DECLARATION

§ 1.63 Oath or declaration.

(a) An oath or declaration filed under § 1.51(a)(2) as a part of an application must:

(1) Be executed in accordance with either § 1.66 or § 1.68;

(2) Identify the specification to which it is directed;

(3) Identify each inventor and the residence and country of citizenship of each inventor; and

(4) State whether the inventor is a sole or joint inventor of the invention claimed.

(b) In addition to meeting the requirements of paragraph (a), the oath or declaration must state that the person making the oath or declaration:

(1) Has reviewed and understands the contents of the specification, including the claims, as amended by any amendment specifically referred to in the oath or declaration;

(2) Believes the named inventor or inventors to be the original and first inventor or inventors of the subject matter which is claimed and for which a patent is sought; and

(3) Acknowledges the duty to disclose information which is material to the examination of the application in accordance with § 1.56(a).

(c) In addition to meeting the requirements of paragraphs (a) and (b) of this section, the oath or declaration in any application in which a claim for foreign priority is made pursuant to § 1.55 must identify the foreign application for patent or inventor's certificate on which priority is claimed, and any foreign application having a filing date before that of the application on

which priority is claimed, by specifying the application number, country, day, month and year of its filing.

(d) In any continuation-in-part application filed under the conditions specified in 35 U.S.C. 120 which discloses and claims subject matter in addition to that disclosed in the prior copending application, the oath or declaration must also state that the person making the oath or declaration acknowledges the duty to disclose material information as defined in § 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

(35 U.S.C. 6, Pub. L. 97-247)

[48 FR 2711, Jan. 20, 1983; 48 FR 4285, Jan. 31, 1983]

§ 1.64 Person making oath or declaration.

(a) The oath or declaration must be made by all of the actual inventors except as provided for in §§ 1.42, 1.43, or 1.47.

(b) If the person making the oath or declaration is not the inventor (§§ 1.42, 1.43, or 1.47), the oath or declaration shall state the relationship of the person to the inventor and, upon information and belief, the facts which the inventor is required to state.

(35 U.S.C. 6, Pub. L. 97-247)

[48 FR 2711, Jan. 20, 1983]

§ 1.66 Officers authorized to administer oaths.

(a) The oath or affirmation may be made before any person within the United States authorized by law to administer oaths. An oath made in a foreign country may be made before any diplomatic or consular officer of the United States authorized to administer oaths, or before any officer having an official seal and authorized to administer oaths in the foreign country in which the applicant may be, whose authority shall be proved by a certificate of a diplomatic or consular officer of the United States, or by an apostille of an official designated by a foreign country which, by treaty or convention, accords like effect to apostilles of designated officials in the United

States. The oath shall be attested in all cases in this and other countries, by the proper official seal of the officer before whom the oath or affirmation is made. Such oath or affirmation shall be valid as to execution if it complies with the laws of the State or country where made. When the person before whom the oath or affirmation is made in this country is not provided with a seal, his official character shall be established by competent evidence, as by a certificate from a clerk of a court of record or other proper officer having a seal.

(b) When the oath is taken before an officer in a country foreign to the United States, any accompanying application papers, except the drawings, must be attached together with the oath and a ribbon passed one or more times through all the sheets of the application, except the drawings, and the ends of said ribbon brought together under the seal before the latter is affixed and impressed, or each sheet must be impressed with the official seal of the officer before whom the oath is taken. If the papers as filed are not properly ribboned or each sheet impressed with the seal, the case will be accepted for examination, but before it is allowed, duplicate papers, prepared in compliance with the foregoing sentence, must be filed.

(35 U.S.C. 6, 15 U.S.C. 1113, 1123)

[47 FR 41276, Sept. 17, 1982]

§ 1.67 Supplemental oath or declaration.

(a) A supplemental oath or declaration meeting the requirements of § 1.63 may be required to be filed to correct any deficiencies or inaccuracies present in an earlier filed oath or declaration.

(b) A supplemental oath or declaration meeting the requirements of § 1.63 must be filed: (1) When a claim is presented for matter originally shown or described but not substantially embraced in the statement of invention or claims originally presented; and (2) When an oath or declaration submitted in accordance with § 1.53(d) after the filing of the specification and any required drawings specifically and improperly refers to an amendment which includes new matter. No new

Patent and Trademark Office
37 CFR Parts 1 and 10
[Docket No. 910764-1306]
RIN: 0651-AA27

Duty of Disclosure

Agency: Patent and Trademark Office, Commerce

Action: Notice of final rulemaking.

Summary: The Patent and Trademark Office (Office) is amending the rules of practice in patent cases to (1) clarify the duty of disclosure for information required to be submitted to the Office; (2) provide flexible time limits for submitting information disclosure statements including the requirement for a fee in certain cases; (3) eliminate consideration of duty of disclosure lawsuits by the Office except in disciplinary and interference proceedings, and under other limited circumstances; and (4) eliminate the striking of patent applications which are improperly executed. The Office further is amending the Patent and Trademark Office Code of Professional Responsibility to define as misconduct a failure to comply with the rules on duty of disclosure. The rules as adopted strike a balance between the need of the Office to obtain and consider all known relevant information pertaining to patentability before a patent is granted and the desire to avoid or minimize unnecessary complications in the enforcement of patents.

Effective Date: March 16, 1992. These rules will be applicable to all applications and reexamination proceedings pending or filed after the effective date.

For Further Information Contact: By telephone Charles E. Van Horn (703-305-9054) or J. Michael Theisz (703-305-9384) or by mail addressed to Commissioner of Patents and Trademarks, Washington, D.C. 20231, and marked to the attention of Charles E. Van Horn (Crystal Park 2 - Room 919).
Supplementary Information: A notice of proposed rulemaking on duty of disclosure and practitioner misconduct published in the Federal Register at 54 FR 11334 (March 17, 1989), and in the Patent and Trademark Office Official Gazette at 1101 Off. Gaz. Pat. Off. 12 (April 4, 1989), was withdrawn. On August 6, 1991, Pat. Off. 52 (August 27, 1991). Sixty written comments were received in response to the notice of proposed rulemaking. A public hearing was held on October 8, 1991. Eleven individuals offered oral comments at the hearing. The sixty written comments and a copy of the transcript of the hearing are available for the Office published in the Office of the Assistant Commissioner for Patents, Room 919, Crystal Park II, 2121 Crystal Drive, Arlington, VA.

Familiarity with the notice of proposed rulemaking is assumed. Changes in the text of the rules published for comment in the notice of proposed rulemaking are discussed. Comments received in writing and at the public hearing in response to the notice of proposed rulemaking are discussed.

The rules as adopted shall take effect as to all applications and reexamination proceedings either pending or filed on or after the effective date of these rules. Thus, any information disclosure statement that is filed on or after that date must comply with the provisions of §§ 1.97 and 1.98 to be entitled to consideration.

Changes in Text: The final rules contain several changes to the text of the rules as proposed for comment. Those changes are discussed below.

Section 1.171(b)(1) has been changed from the proposed text to reflect the recent increase in the amount of the fee for filing a petition from \$120.00 to \$130.00.

Section 1.56(a) has been clarified to indicate that the duty of an individual to disclose information is based on the knowledge of that individual that the information is material to patentability. A sentence has been added to § 1.56(a) to express the principle that the Office does not condone the granting of a patent on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. In addition, § 1.56(a) as proposed has been changed to indicate that if all information material to patentability of any claim issued in a patent is cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)(4) and 1.98, the Office will consider as satisfied the

duty to disclose to the Office all information known to be material to patentability, as contrasted to the broader duty of candor and good faith. This rule does not attempt to define the specific conduct that would lack the candor and good faith in dealing with the Office which is expected of individuals who are associated with the filing or prosecution of a patent application.

In § 1.56(b), the phrase "or being made of record" has been inserted to make it clear that information is not material to patentability within the meaning of § 1.56 if it is cumulative to other information already of record in the application or contemporaneously being made of record by applicant. For example, there would be no benefit to the Office for applicant to submit to the Office 10 different documents having the same teaching simply because the information was not cumulative to the information already of record.

The term "evidentiary" has been replaced by the term "established" in § 1.56(b)(1). In addition, the definition of a prima facie case of unpatentability, as set out in the preamble of the notice of proposed rulemaking, has been incorporated into the rule itself. A prima facie case of unpatentability of a claim is established when the information compels a conclusion that the claim is unpatentable.

- (1) under the preponderance of evidence, burden-of-proof standard,
- (2) giving each term in the claim its broadest reasonable construction consistent with the specification, and
- (3) before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

This prima facie standard conforms to U.S. standard used by an examiner to determine whether a claim is prima facie unpatentable.

Section 1.56(b)(2) has been modified from the text of the proposed rule. The focus of this paragraph has been changed so that it now relates to information which either refutes, or is inconsistent with, a position that applicant takes in either

- (1) opposing an argument of unpatentability relied on by the Office, or
- (2) asserting an argument of patentability.

The change from the proposed rule makes clear that information material which either refutes, or is inconsistent with, a position taken by applicant before the Office.

Section 1.97(e) has been changed from the proposed text to make it clear that a certification could contain either of two statements. One statement is that each item of information in an information disclosure statement was cited in a search report from a patent office outside the U.S. not more than three months prior to the filing date of the statement. Under this certification, it would not matter whether any individual with a duty actually knew about any of the information cited before receiving the search report. In the alternative, the certification could state that no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual having a duty to disclose more than three months prior to the filing of the statement.

The changes to the text of § 1.97(e) as proposed place the appropriate priority on getting relevant information to the Office promptly, with minimum burden to applicant. The text of the proposal has also been changed by adding the phrase "after making reasonable inquiry" to make it clear that the individual making the certification has a duty to make reasonable inquiry making the facts that are being certified. For example, if an inventor gave a publication to the practitioner prosecuting an application with the intent that it be cited to the Office, the practitioner should inquire as to when that inventor became aware of the publication before submitting a certification under § 1.97(e)(ii) to the Office.

A new paragraph (h) has been added to the text of proposed § 1.97. The purpose of new paragraph (h) is to ensure that no one could construe the mere filing of an information disclosure statement as an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b). It is in the best interest of the Office and the public to permit and encourage individuals to cite information to the Office without fear of making an admission against interest.

litigation when combined with information not known at the time of the prosecution to any person substantively involved in the preparation or prosecution of the application.

Reply: Paragraph (a) of §1.56 makes it clear that the Office recognizes that the duty to disclose material information is limited to such information which is known by an individual substantively involved in the preparation or prosecution of the application. Thus, while information may be material under the definition of §1.56(b)(1), there can be no duty to disclose the information if it is material only in combination with unknown information.

Comment 30. One comment stated that proposed §1.56(b) should be modified so that paragraph (b)(1) refer to information that renders a claim unpatentable ("but for"), paragraph (b)(2) remains as proposed, and a paragraph (b)(3) is added to include the definition of materiality as "the closest information over which any pending claim materially defines." This comment suggested that this modified definition would have the advantage of not requiring the applicant to submit references which applicant knows are immaterial and to then engage in "straw man" arguments based on such references.

Reply: The suggested modification to §1.56 has not been adopted. The suggested language would seemingly require information to be filed in each application, whether the information is relevant or not, since the "closest information" would be required. Section 1.56 does not require information which is not relevant to be submitted, but only information which meets the definition of material as set out in the rule.

Comment 31. One comment stated that if proposed §1.56(b)(1) is promulgated, there would be no need for proposed §1.56(b)(2) with regard to information which would make a prima facie case of unpatentability and other information required by paragraph (b)(2) might be obscure. Another comment argued that paragraph (b)(2) was unnecessary, confusing and ambiguous and suggested changes in the language to make the requirement clear and less ambiguous.

Reply: The suggestion as to the language change to §1.56(b)(2) has been adopted. The final rule language avoids the perceived problem of requiring an applicant to submit information supporting a position taken by the examiner. It is not appropriate, however, to eliminate paragraph (b)(2) because it is an essential part of the definition of information material to patentability and will help to ensure that all material facts are brought to the attention of the examiner during the examination process.

Comment 32. One comment questioned the language of proposed §1.56(b)(2) as to how an applicant could consider a prior art reference as supporting a position of unpatentability taken by the Office while at the same time disputing that interpretation.

Reply: The language of §1.56(b)(2) has been modified to clarify that information is material to patentability if it refutes, or is inconsistent with, a position the applicant takes in (1) opposing an argument of unpatentability relied on by the Office, or (2) asserting an argument of patentability.

Comment 33. One comment stated that §1.56(b)(2) was flawed in requiring a duty to conduct a file search to make sure that no information exists which even arguably contradicts a position taken or to be taken in response to the examiner, or which supports the examiner's position which may be improper.

Reply: Section 1.56(b)(2) does not require a search of files. Under §1.56(a), the duty of disclosure is confined to that information which is known to an individual to be material as defined in paragraph (b).

Comment 34. One comment stated that proposed §1.56(c) should be modified to state that the duty of any individual designated as having a duty of disclosure would terminate when such individual ceases to be substantively involved in the preparation or prosecution of the application. The comment used, as an example, an inventor who would not be aware of art cited by the examiner which would cause information known to the inventor to fall within the definition of materiality for the first time.

Reply: The suggestion in the comment is not adopted. The duty to disclose information material to patentability rests on the individual designated as §1.56(c) until the application issues as a patent or becomes abandoned. Paragraph (a) of §1.56 makes it clear, however, that each individual has a duty to disclose only information which is known to that individual to be material.

Comment 35. One comment stated that proposed §1.56(c)(3) should not include the assignee, or anyone to whom there is an obligation to assign the application, in the class of those who

have a duty to disclose material information since there might be a "witch hunt" during litigation to find one employee with knowledge of, or possession of, information that should have been disclosed.

Reply: No modification to §1.56(c)(3) is needed since §1.56 sets forth that only individuals who are associated with the filing and prosecution of a patent application have a duty of candor and good faith, including a duty to disclose to the Office all information known to be material to patentability.

Comment 36. One comment stated that proposed §1.56(d) should be revised to expressly allow an inventor to satisfy the duty by disclosing information to the practitioner who prepares or prosecutes the application so that redundant information disclosure statements will not be required from both the inventor and the attorney or agent.

Reply: The suggestion in the comment is not adopted since the duty as described in §1.56 will be met as long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by §§1.97(b)-(d) and 1.98 before issuance of the patent. Statements from both an inventor and the practitioner are not required to be submitted.

Comment 37. One comment stated that proposed §§1.52(c) and 1.67(c) should be modified to either (1) expressly permit alterations to be made in an application subsequent to the signing of the oath or declaration or (2) more properly, prohibit such alterations since if alterations are desirable, they can be made and the application can be filed with an unsigned oath or declaration. Another comment stated that willfully filling out false oaths should never be condoned.

Reply: The Office does not condone willfully filling out false oaths. Further, §10.23(c)(1) indicates that the Office considers it misconduct for a practitioner to knowingly file or cause to be filed an application containing a material alteration made after the signing of an accompanying oath or declaration without identifying the alteration. The Office will not consider striking an application in which an alteration was made, but a supplemental oath or declaration is required to be filed in an application containing alterations made after the signing of the oath or declaration.

Comment 38. One comment stated that the implementation of proposed §1.63(b)(3) and 1.175(c)(7) allows for a two-month delay in the deadline for requiring declarations complying therewith.

Reply: The averments in oath or declaration forms presently in use that comply with the previous §1.63 or §1.175 will also comply with the requirements of the new rules. Therefore, the Office will continue to accept the old oath or declaration forms as complying with the new rules.

Comment 39. Five comments questioned the need for the proposed rules since statistics show that information disclosure statements are submitted early in prosecution and questioned what new service is being provided for the proposed rule in §1.97.

Reply: The Office desires to continue to encourage information to be submitted promptly so that it can be considered by the examiner when the first Office action is prepared. Some people have expressed a desire to have the option of waiting to submit information until after the first Office action, without concern that they will be subject to a charge of inequitable conduct. Section 1.97(c), as amended, will provide this option to applicants in that information will be considered later than three months after the filing date of the application (§1.97(a) prior to amendment) without a showing of promiscuity (§1.99). The fee will compensate the Office for the added expense caused by the late submission of the information and will serve as a disincentive to the intentional withholding of information even for a short period of time.

Comment 40. Two comments suggested that proposed §1.97(a) be modified so that the mechanism of proposed §1.98 would not be the only acceptable technique for submitting information.

Reply: The Office has set forth the minimum requirements for information to be considered in §§1.97 and 1.98. These rules will provide certainty for the public of exactly what the requirements are, when the Office will consider information and when the Office will not consider information. Thus, applicants are provided with means for complying with the duty of disclosure by following the rules. If information is submitted in a manner so that it is not considered by the Office, applicant will assume the